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EXAMINER	
SUCHECKI, KRYSTYNA	

ART UNIT	PAPER NUMBER
2882	

DATE MAILED: 03/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

N/A

Office Action Summary	Application No.	Applicant(s)	
	10/656,438	SEPPI ET AL.	
	Examiner	Art Unit	
	Krystyna Suchecki	2882	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-53 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-53 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 15 January 2004 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 7/9/04.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claims are objected to because of the following informalities: Claims 1 and 18 reference a "process" while the depending claims reference a "method". Claims 36-38 refer to a "method" while numerically they depend from a "process". Appropriate correction is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1, 3, 6-12, 14-17 and 31-53 are rejected under 35 U.S.C. 102(e) as being anticipated by Bailey (US 2003/0048868).

4. Regarding Claims 1 and 14, Bailey teaches a radiation method and system, comprising: illuminating an object with a first beam at a first energy level (Paragraph 39); determining a first image of the object formed by the first beam (Paragraphs 45); determining configuration data using the first image (Paragraph 49); illuminating the object with a second beam at a second energy level (Paragraphs 49-54); determining a second image of the object formed by the second beam (Paragraphs 48-51); determining radiation absorption data using the second image (Paragraphs 49-51); and determining a radiation treatment plan using the configuration data and the radiation absorption data (Paragraphs 50-54).

5. Regarding Claim 3, Bailey teaches a radiation process wherein the first beam and the second beams can have low intensities (Paragraphs 4 and 37).

6. Regarding Claim 6, Bailey teaches the method of claim 1, further comprising adjusting an intensity of the second beam during a session (Paragraph 53, since a power supply is varied).

7. Regarding Claims 7 and 8, Bailey teaches the method of claim 1, wherein the illuminating the object with the first beam and the illuminating the object with the second beam are performed in alternating pulses and wherein the illuminating the object with the first beam and the illuminating the object with the second beam are performed sequentially (Paragraphs 43-46 and 50).

8. Regarding Claims 9 and 15, Bailey teaches a method and system, wherein the determining configuration data comprises comparing data associated with the first image with data regarding configuration of the object specified in a treatment prescription (Paragraphs 53-54).

9. Regarding Claims 10 and 16, Bailey teaches a method and system, wherein the determining radiation absorption data comprises calculating a radiation absorption rate in the object. [Bailey teaches dose tracking (Paragraph 54), which is numerically linked to the absorption rate since the rate must be known in order to determine the dose.]

10. Regarding Claims 11 and 17, Bailey teaches a method and system, further comprising storing the configuration data and the radiation absorption data in a computer readable medium (Paragraphs 48 and 53-54).

11. Regarding Claim 12, Bailey teaches the method of claim 1, wherein the configuration data comprises one or a combination of location, size, and shape of the object (Paragraphs 49-52).

12. Regarding Claims 31 and 42, Bailey teaches a radiation process and system, comprising: illuminating an object with a treatment beam in accordance with a treatment plan (Paragraphs 48-51); determining an image of the object formed by the treatment beam (Paragraphs 33 and 53-54); determining radiation absorption data using the image (Paragraph 54, since dose is determined based upon absorption data); and evaluating an execution of the treatment plan based on the radiation absorption data (Paragraphs 48 and 53-54).

13. Regarding Claims 32-34 and 43, Bailey teaches a process and system of adjusting the treatment beam, wherein the adjusting comprises one or a combination of changing a direction, a shape, and an intensity of the treatment beam based upon determined configuration data of the object (Paragraphs 51-54).

14. Regarding Claim 35, Bailey teachesthe process of claim 34, wherein the determining the configuration data comprises illuminating the object with an image beam; determining an image formed by the image beam; and determining the configuration data using the image formed by the image beam (Paragraphs 47-50).

15. Regarding Claim 36, Bailey teaches evaluating performed based on the configuration data (Paragraphs 47-50 and 53-54).

16. Regarding Claim 37, Bailey teaches a method and system for adjusting the treatment beam based on the configuration data (Paragraph 54).

17. Regarding Claims 38 and 44, Bailey teaches a method and system comprising gating an operation of the treatment beam based on the configuration data (Paragraphs 49 and 54, since Bailey evaluates and treats at a certain angle, then adjusts the device to evaluate and treat at a second angle, the method and system are gated based upon the configuration data of an updated treatment plan).

18. Regarding Claims 39-41, Bailey teaches the process of claim 31, further comprising verifying the treatment plan before illuminating the object with the treatment beam and developing a treatment plan such that the developing the treatment plan and illuminating an object with a treatment beam are performed during a single patient session (Paragraphs 21, 23, 33 and 53-54).

19. Regarding Claim 45, Figures 1-3 of Bailey teach an apparatus for irradiating an object, comprising: a platform (60) for supporting an object; a first beam source (22A) configured to generate a first radiation beam (30B) at a first intensity level and a second radiation beam at a second intensity level toward the platform (Paragraphs 43-44); a beam adjuster (at 46, see Paragraph 41) in front of the first beam source; a projection detector (24A) configured to generate a first image of the object illuminated by the first radiation beam at the first intensity level; and a control module (82 and Paragraph 53) coupled to the projection detector and to the beam adjuster.

20. Regarding Claim 46, Bailey teaches the apparatus of claim 45, further comprising a second beam source (22B) configured to generate an image beam toward the platform, wherein the projection detector is further configured to generate a second image of the object illuminated by the image beam (Paragraphs 43-44 and 50).

21. Regarding Claims 47 and 48, Bailey teaches the apparatus of claim 45, wherein the control module is configured to develop a radiation treatment plan based on the first image or based on one or both of the first image and the second image (Paragraphs 53-54).

22. Regarding Claim 49, Bailey teaches the apparatus of claim 45, wherein the control module is configured to adjust one or a combination of a shape, an intensity, and a direction of the second radiation beam (Paragraphs 49, 51 and 53-54).

23. Regarding Claim 50, Figures 1-3 of Bailey teach an apparatus for irradiating an object, comprising: a platform (60) for supporting an object; a first beam source (22B) configured to generate a first radiation beam (30B) at a first intensity level and a second radiation beam (30B) at a second intensity level toward the platform (Paragraph 44); a second beam source (22A) configured to generate an image beam toward the platform; a beam adjuster (Paragraph 41) in front of the first beam source; a projection detector (24) configured to generate one or both of a first image of the object illuminated by the first radiation beam at the first intensity level and a second image of the object illuminated by the image beam (Paragraphs 43-46 and 50); and a control module (82) coupled to the projection detector and to the beam adjuster (Paragraphs 53-54).

24. Regarding Claims 51-53, Bailey teaches the apparatus of claim 50, wherein the control module (82) is configured to determine, verify and modify a treatment plan based on one or both of the first and second images (Paragraphs 47, 48 and 52-54).

Claim Rejections - 35 USC § 103

25. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

26. Claims 2, 18, 20-24 and 26-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bailey in view of Ruchala (US 6,618,467).

27. Regarding Claims 2, 18, and 26, Bailey teaches a method and system for radiation imaging and therapy as above having first and second imaging beams.

28. Bailey fails to teach voltages for the first and second imaging beams.

29. Ruchala teaches that conventional first imaging beams could be in the kilovoltage range, and second imaging beams can be on a megavoltage range (Column 1, lines 56-67). The difference in ranges allows for a low energy pre-scanning image to be made, and a second image to be made during high energy treatment. The first and second images are used in concert to create a treatment plan (Column 1, line 56-Column 2, line 14).

30. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the kilovoltage and megavoltage energy levels of Ruchala in the system of Bailey for the benefit of creating a pre-scanning image to be used with, and for the creation of, a treatment plan.

31. Regarding Claims 20 and 27, Bailey teaches a method and system further comprising adjusting an intensity of the second beam during a session (Paragraph 53, since a power supply can be both constant and varied).

32. Regarding Claims 21 and 28, Bailey teaches a method and system, wherein the determining configuration data comprises comparing data associated with the first image with

data regarding configuration of the object specified in a treatment prescription (Paragraphs 53-54).

33. Regarding Claims 22 and 29, Bailey teaches a method and system, wherein the determining radiation absorption data comprises calculating a radiation absorption rate in the object. [Bailey teaches dose tracking (Paragraph 54), which is numerically linked to the absorption rate since the rate must be known in order to determine the dose.]

34. Regarding Claims 23 and 30, Bailey teaches a method and system, further comprising storing the configuration data and the radiation absorption data in a computer readable medium (Paragraphs 48 and 53-54).

35. Regarding Claim 24, Bailey teaches a method, wherein the configuration data comprises one or a combination of location, size, and shape of the object (Paragraphs 49-52).

36. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bailey in view of Swerdloff (US 5,661,773).

37. Regarding Claim 4, Bailey teaches a radiation process having a first energy level beam for imaging and a second energy level imaging beam as above for claim 1.

38. Bailey fails to teach intensities wherein the first beam has an intensity between approximately 1 Rad and 20 Rad, and the second beam has an intensity between approximately 250 Rad and 1000 Rad.

39. Swerdloff teaches that a preliminary image of a object for treatment should be made with a beam of a first energy level wherein the beam has an intensity between approximately 1 and 20 Rad (Figures 19-21). A first image is made, and the a second energy level beam is used to treat

an area of an object with a second energy level between 250 and 1000 Rad (Column 14, lines 1-7). The treatment is tracked as an imaged dose map (item 90). The second image is used to track whether the dose was administered accurately (Abstract).

40. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the Rad values of Swerdloff in the process of Bailey since conventional image and treatment intensities are used to treat an object and create first and second images of an object. By tracking the Rad values administered, Bailey can better track the dose administered for accuracy (Swerdloff, Abstract).

41. Claims 5 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bailey in view of McNutt (US 6,735,277).

42. Regarding Claims 5 and 13, Bailey teaches a method wherein the radiation treatment plan is configured for use in a computed fan therapy where a slices are defined by a collimator (Paragraph 25) as a source rotates about a patient (Paragraphs 41-47) to create a computer generated two-dimensional dose of radiation (Paragraphs 48-50) for adaptive, single visit treatment (Paragraphs 33 and 53-54). A power supply controls a radiation source (Paragraph 53).

43. Bailey fails to teach computed cone therapy or a second beam having a constant intensity during a session.

44. McNutt teaches an imaging and treatment method where fan therapy is an alternative of cone therapy (Column 4, line 2; Column 5, lines 45-65). There are tradeoffs between the two, one being that the cone therapy requires a more complicated collimator for constant intensity step-and-shoot applications, versus the need to spiral scan in a fan-beam system (Id.). The cone

beam system would thereby afford more stability as the system could operate in a stationary mode with less vibration from moving parts, thereby making the application of dose radiation more accurate.

45. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the alternative constant intensity computed cone beam therapy of McNutt in the adaptive treatment system of Bailey since the step-and-shoot operation afforded by McNutt would allow less interfering vibration during treatment. The cone beam therapy would still further Bailey's goal of planning and treatment in a single visit, while not interfering with the adaptive treatment planning operations.

46. Claims 19 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bailey and Ruchala and further in view of McNutt (US 6,735,277).

47. Regarding Claims 19 and 25, Bailey teaches a method wherein the radiation treatment plan is configured for use in a computed fan therapy where a slices are defined by a collimator (Paragraph 25) as a source rotates about a patient (Paragraphs 41-47) to create a computer generated two-dimensional dose of radiation (Paragraphs 48-50) for adaptive, single visit treatment (Paragraphs 33 and 53-54). A power supply controls a radiation source (Paragraph 53).

48. Bailey fails to teach computed cone therapy or a second beam having a constant intensity during a session.

49. McNutt teaches an imaging and treatment method where fan therapy is an alternative of cone therapy (Column 4, line 2; Column 5, lines 45-65). There are tradeoffs between the two, one being that the cone therapy requires a more complicated collimator for constant intensity

step-and-shoot applications, versus the need to spiral scan in a fan-beam system (Id.). The cone beam system would thereby afford more stability as the system could operate in a stationary mode with less vibration from moving parts, thereby making the application of dose radiation more accurate.

50. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the alternative constant intensity computed cone beam therapy of McNutt in the adaptive treatment system of Bailey since the step-and-shoot operation afforded by McNutt would allow less interfering vibration during treatment. The cone beam therapy would still further Bailey's goal of planning and treatment in a single visit, while not interfering with the adaptive treatment planning operations.

Conclusion

51. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Lemelson (US 5,464,013) is of interest for teaching a dual energy x-ray system wherein an initial imaging beam is used to determine the application of a treatment beam, and an image acquired by the treatment beam is used to modify the treatment plan.

52. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Krystyna Suchecki whose telephone number is (571) 272-2495. The examiner can normally be reached on M-F, 9-5.

53. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Edward Glick can be reached on (571) 272-2490. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

54. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ks

Craig E Church

Craig E. Church
Primary Examiner